k121603

NOV 20 2012

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92 STATEMENT

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

2. SUBMITTER NAME AND ADDRESS

Name: Randox Laboratories Limited

Address: 55 Diamond Road, Crumlin,
County Antrim, BT29 4QY,
United Kingdom.

Telephone: +44 (0) 28 9442 2413
Fax: +44 (0) 28 9445 2912
E-mail: marketing@randox.com

3. 510k NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR SUBMISSION, REGULATORY CLASSIFCATION, PANEL, PRODUCT CODE AND 21 CFR NUMBER

510k No: k121603

Device Proprietary Name: Randox Immunoassay Speciality Control (II) Levels 1, 2 and 3

Common Name: Immunoassay Speciality Control (II) Levels 1, 2 and 3

Purpose for Submission: New Device

Regulatory Classification: Multi-analyte Controls, All kinds (Assayed and Unassayed)

Panel: Clinical Chemistry

Product Code: JJY

21 CFR Number: 21 CFR 862.1660

4. PREDICATE DEVICE PROPRIETARY NAME AND 510 (k) NUMBER

Predicate Device Proprietary Name:
Biorad Lyphochek^{R} Immunoassay plus Control Levels 1, 2 and 3

510 (k) Numbers: K981532

5. INTENDED USE

The Randox Immunoassay Speciality Control (II), Level 1, Level 2, Level 3 are intended for in vitro diagnostic use as assayed quality control material for Calcitonin, Gastrin, and Procalcitonin to monitor the precision of the laboratory testing systems listed in the package insert. This device is for prescription use only.

6. DEVICE DESCRIPTION

Randox Immunoassay Speciality Control (II) is manufactured at three levels, Level 1, Level 2 and Level 3.
Each control is prepared from human serum with added constituents of human origin, chemicals, stabilizers and preservatives. They are supplied in lyophilised form in 5x1ml vials and require reconstitution with 1ml of distilled water.

The analyte concentrations in each of the three levels have been chosen to span a range that includes the chemically significant or medical decision level(s). The analyte concentrations have been reviewed by a panel of experts to ensure that the concentrations are clinically relevant for use in routine hospital laboratories.

7. PREDICATE DEVICE COMPARISON TABLE

CHARACTERISTICS	RANDOX SPECIALITY IMMUNOASSAY CONTROL (II) LEVELS 1, 2 AND 3	BIO-RAD LYPHOCHEK[R] IMMUNOASSAY PLUS CONTROL LEVELS 1, 2 & 3 K981532
INTENDED USE	The Randox Immunoassay Speciality Control (II), Level 1, Level 2, Level 3 are intended for in vitro diagnostic use as assayed quality control material for Calcitonin, Gastrin, and Procalcitonin to monitor the precision of the laboratory testing systems listed in the package insert. This device is for prescription use only.	For use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert
SIZE	1ml	5ml
FORMAT	Lyophilised	Lyophilised
MATRIX	Human Serum	Human Serum
STORAGE (Unopened)	2 to 8 ^{0}C Until expiration date	2 to 8 ^{0}C Until expiration date
OPEN VIAL CLAIM	Store refrigerated +2 to 8°C In reconstituted serum Procalcitonin is stable for 1day, Gastrin and Calcitonin are stable for 8hours at +2 to 8°C if kept capped in original container and free from contamination. The control is stable if frozen once for 28days at -20°C.	Once the control is reconstituted all analytes will be stable for 7days when stored tightly capped at +2 to 8°C with the exceptions of Calcitonin and Gastrin, which should be assayed immediately after reconstitution. After reconstituting and freezing the control, all analytes are stable for 20days when stored tightly capped at -10°C to -20°C with the exception of Calcitonin as there is no frozen stability claim supplied.
SHIPPING TEMPERATURE	+2 to 8°C	+2 to 8°C
ANALYTES	Procalcitonin, Gastrin and Calcitonin.	There are a total of 92 analytes listed in the package insert. However only Gastrin and Calcitonin are applicable to this comparison.

8. SUMMARY OF STABILITY STUDIES

Opened: Store refrigerated (+2°C to +8°C). In reconstituted serum, Procalcitonin is stable for 1 day, Gastrin and Calcitonin are stable for 8 hours at +2°C to +8°C if kept capped in original container and free from contamination. The control is stable of frozen once for 28 days at -20°C. Only the required amount of the product should be removed. After use, any residual product should not be returned to the original vial.
Unopened: Store refrigerated (+2oC to +8oC). Stable to the expiration date printed on individual vials.

9. SUMMARY OF VALUE ASSIGNMENT

The value assignment for Calcitonin, Procalcitonin and Gastrin is performed at Randox Laboratories. The analysis is carried out on selected analysers. Two vials of sample are analyzed by running five replicates of each vial over the course of 2 days using the normal procedures for calibration on each day.

The mean value generated from the 20 replicates is used as the assigned value and ranges are set as +/- 25% of the assigned value.

The acceptance criteria for data is % coefficient of variation ≤ 15%.

10. TRACEABILITY

ANALYTE	SUPPLIER	PRODUCT NUMBER	ORIGIN	SOURCE
Calcitonin	Sigma	T-3525	Synthetic Analytical Grade Chemical	Commercial source, added volumetrically
Gastrin	Sigma	G-9020	Human Gastrin	Commercial source, added volumetrically
Procalcitonin	Randox	RCP9522	Extracted and purified from *E.coli*	Commercial source, added volumetrically

11. CONCLUSION

Testing results indicate that the proposed device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Randox Laboratories Limited
c/o Pauline Armstrong
55 Diamond Road, Crumlin
County Antrim, BT29 4QY,
United Kingdom.

Re: k121603
Trade/Device Name: Randox Immunoassay Speciality Control (II) Levels 1, 2 and 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: October 11, 2012
Received: October 15, 2012

Dear Dr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121603

Device Name: Randox Immunoassay Speciality Control (II) Levels 1, 2 and 3

Indication for Use:

The Randox Immunoassay Speciality Control (II) Levels 1, 2 and 3 are intended for in vitro diagnostic use as assayed quality control material for Calcitonin, Gastrin, and Procalcitonin to monitor the precision of the laboratory testing systems listed in the package insert.

This in vitro diagnostic device is intended for prescription use only.

Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K121603